

PROPOSALS TO IMPROVE CLASSIFICATION ARRANGEMENTS FOR DESIGNATED SHELLFISH HARVESTING AREAS IN ENGLAND AND WALES

CLASSIFICATION OF SHELLFISH HARVESTING AREAS

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1 SUMMARY

- 1.1 In October 2002 the Agency instigated a review of the classification system in England and Wales¹. Issues relating to sampling frequency and the *E.coli* test method (Most Probable Number (MPN) v Malthus), as well as communication of test results, virus controls and long term classification were covered in the review. A total of 27 responses to the consultation exercise were received and they can be found on the Agency's web site².
- 1.2 The main focus of this consultation paper is the Long Term Classification proposals (LTC) which have been developed in response to the comments from the review exercise, but the other matters covered by the review are also discussed. The proposals seek to improve the classification arrangements in a way which is practical, enforceable, legally acceptable, and which delivers improved public health protection. The proposals are being issued for a three month consultation period which will end in July 2004 and responses will be used to inform implementation decisions.
- 1.3 The proposals seek to improve the classification arrangements by delivering improved public health protection in a way which is manageable and affordable. The scheme which has been developed is intended to be the first stage of an on-going process. In the first instance LTC is expected to apply to class B beds with 5 years worth of compliance data (90% below 4600 *E. coli*/100g of flesh). It is envisaged that the arrangements would be reviewed after 2 years with a view to extending them, if successful, to class A beds. All beds not covered by the LTC arrangements would be subject to temporary annual classifications.
- 1.4 Under the proposals, a tiered system of investigation and control measures would be introduced which would include an 'action state' to facilitate rapid response and action in cases where *E. coli* levels exceed trigger values. Local Action Groups, comprising representatives from industry, Local Authorities, the Environment Agency and the Sea Fisheries Inspectorate, will be responsible for investigating incidents using Local Action Plans where *E. coli* readings exceed legal levels.

¹ http://www.food.gov.uk/foodindustry/Consultations/completed_consultations/comconsulteng/shellreviewen

² <http://www.food.gov.uk/multimedia/pdfs/shellfishresponses03.pdf>

2 BACKGROUND

2.1 Within the European Union, Council Directive 91/492/EEC (the shellfish Hygiene Directive) lays down the health conditions for the production and placing on the market of live bivalve molluscs intended for human consumption. It stipulates that shellfish may only be harvested from areas that have been monitored and classified. The Directive provides for individual Member States to determine the most appropriate way to implement the classification requirements. In England and Wales, Directive 91/492/EEC is implemented by the Food Safety (Fishery Products and Live Shellfish) (Hygiene) Regulations 1998. Further details on the classification arrangements are set out in Annex 1. However, in future this legislation will be replaced by new European hygiene regulations which are expected to come into effect in 2006. The proposals described in this consultation document have been drawn up taking the proposed new legislation into account.

2.2 The Food Standards Agency (FSA), as the competent authority for the UK, is responsible for monitoring shellfish in a way which is legal, enforceable, cost effective, and practical. Industry are responsible for ensuring that shellfish placed on the market meet the requirements of Directive 91/492/EEC.

2.3 In England and Wales classification of shellfish harvesting areas is based on monthly microbiological (*E. coli*) data. The first full classification was issued in 1993. At that time 8% of beds were issued provisional class A status, but sustained monitoring showed that several of these areas did not comply with the Directive requirements. Since then, water quality improvements have markedly reduced the number of class C and Prohibited beds; and have increased the proportion of beds in class B. Over time a small number of beds originally assigned Class B status have achieved class A criteria and have been up-graded accordingly. Further improvements required to increase the proportion of A class waters will necessitate concerted reductions in both sewage and diffuse contamination in many areas.

3. DEVELOPMENTS SINCE 2002 REVIEW

3.1 Improvements to the classification system require both short and long-term changes and planning. Paragraphs 3.2 to 3.13 outline the position in relation to the issues covered in the 2002 review.

Communication Of Classification Results

3.2 The number of laboratories undertaking *E. coli* classification testing which transmit their results electronically to CEFAS has increased and this has facilitated improved speed and accuracy of result reporting.

3.3 Most of the laboratories are now reporting results electronically and nearly all of these have reduced their reporting times significantly. The Health Protection Agency (HPA) is undertaking concerted action to ensure that all its laboratories report data to CEFAS and Local Authorities (LAs) in the required format and electronically within 5 days from the sampling date, initially, but with a final aim of 3 days (allowing for 48hrs test time and 24hrs to report). It is hoped that all results will be received electronically in the near future.

3.4 In view of requests from industry and local authorities, CEFAS was asked to explore whether it would be possible to initiate investigative procedures on the basis of presumptive positives at 24 hours. It has advised that there is no reason why food authorities, as the customers of the laboratories, could not arrange this with their local laboratory. However, published work has shown that approximately one-third more results would be positive at this stage than after confirmation (Donovan, et al. 1998) and this would trigger additional investigations which would have implications for resources.

Virus controls

3.5 It is generally recognised that the absence of *E. coli* is no guarantee that faecally derived pathogenic micro-organisms are not present. In 1998, the Advisory Committee on the Microbiological Safety of Food (ACMSF) advised that viruses are the main public health risk associated with shellfish.³

3.6 Depuration studies indicate that, in general, bacteria are rapidly reduced to non-detectable levels, usually within 48 hours, while viruses are more slowly reduced and may persist for several days. The effect in the marine environment is not known.

³ ACMSF report on foodborne viral infections, available from The Stationary Office (ISBN 0-11-322254-8).

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3.7 At the present time there are no accepted standard methods to test for viruses. However, the EU Commission has engaged CEFAS to develop a shellfish viral indicator detection method using FRNA bacteriophage. The outcome of this work, together with EU proposals on micro-criteria and other EU legislative developments will be used to inform future decisions on viral controls.

***E. coli* Testing Arrangements**

- 3.8 Although *E. coli* is generally accepted as being a good indicator of recent faecal contamination (either animal or human), concentrations of *E. coli* in shellfish in the environment have been found to fluctuate widely (Lees and Nicholson 1995). In order to minimise variation due to sampling and transport methods, a standard sampling protocol is issued to all LAs. Major aspects covered by the protocol are sample size and preparation, transport conditions and a requirement to test within 24 hours of sampling. In addition it stipulates that sampling should be undertaken, where practical, on as random a basis as possible with respect to likely influencing environmental factors e.g. tidal state, rainfall, wind, so as to avoid introducing any bias to the results.
- 3.9 In the UK the MPN test has been used to detect *E. coli* in shellfish, because, when used with the correct microbiological media, the technique is very good at recovering stressed organisms such as those exposed to the marine environment. In some other countries methods based on impedance technology are also used. Internationally, MPN tests are used for the assessment of shellfish quality, both in harvesting areas and in the final product.
- 3.10 All classification testing laboratories in England and Wales are accredited to carry out the MPN method to UKAS standards and take part in the HPA EQA scheme. A series of protocols and quality checks are also applied at various stages of the testing process (sampling, laboratory analysis, data storage and assessment).
- 3.11 The UK NRL has reviewed the testing methods and published the assessment on its website.⁴ The UK NRL and UK testing laboratories consider that methods based on impedance technology would be considerably more expensive to operate unless testing was centralised, and this would pose difficulties with respect to sample collection and transportation issues. Unless methods based on impedance technology are used for testing a wider range of foodstuffs they could not be considered commercially. The FSA is not therefore proposing to change current test methods.

⁴http://nrlcefafas.org/InformationCentre/docs/Impedance_vs_MPN.PDF

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4 LONG TERM CLASSIFICATION (LTC) PROPOSALS

4.1 Proposals have been developed to:

- determine the underlying long-term classification status of shellfish harvesting areas;
- facilitate more responsive actions to deal with potential contamination of shellfish harvesting areas; and

4.2 In developing the proposals the Agency has considered the classification systems applied in France and Holland and has sought to incorporate elements which are suitable for the situation in England and Wales (i.e. action states, trigger values and local investigations). The proposals are not considered appropriate for parts of Scotland and Northern Ireland where production is mainly from offshore rope or raft cultivation distant from sources of *E. coli*. However, the Agency's offices in Scotland may consider the development of long-term classification proposals for Scottish shore based shellfish beds.

4.3 The proposals seek to improve the classification arrangements by delivering improved public health protection in a way which is manageable and affordable. The scheme which has been developed is intended to be the first stage of an on-going process. In the first instance the system would be expected to be restricted to B class beds with 5 years' worth of compliance data (90% below 4600 *E. coli* per 100g of flesh). The system would be reviewed after 2 years, with a view to extending it, if successful, to A class beds. All beds not covered by the LTC arrangements would be subject to temporary annual classifications.

4.4 Classifications would continue to be assessed in accordance with criteria laid down in Council Directive 91/492/EEC. In addition statistical measures would be used to assess margins of error and determine trends. These data would be used to inform decisions relating to temporary actions in the case of contamination events.

4.5 Decisions relating to the classification status of shellfish beds or other measures will primarily be based on the criteria in the Directive/Regulations intended to protect public health. However, as part of the investigations undertaken, and as part of the action state arrangements, additional data assessment is proposed, using two statistical approaches based on *E. coli* results averaged over a year.

4.6 One assessment would use the average variability of results at monitoring points around England and Wales to compare the microbiological quality of the shellfish with respect to compliance with the classification criteria under the UK Regulations. The other assessment would involve comparison of the most recent years' data with historic data at the monitoring point, or points, under investigation in order to see whether a significant deterioration or improvement in quality has occurred.

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- 4.7 These analyses would allow the usual compliance comparisons to be made, but would also allow more extensive analyses to assess the margins of error and determine trends. All statistical analysis would be carried out by CEFAS and would be made available to the Agency and LAGs.
- 4.8 Measures have also been proposed to strengthen public health protection and facilitate more active management at the local level. Local Action Groups (LAGs) comprising representatives from industry, Local Authorities (LAs), the Environment Agency (EA) and the Sea Fisheries Inspectorate (SFI) would be set up to assist with investigations. The approach to be followed by LAGs would be set out in Local Action Plans (LAPs). These arrangements are set out in Annex 2.
- 4.9 In addition, 'action state' provisions have been developed. These would be activated, where *E. coli* results exceed defined trigger values for A, B and C class areas. In these cases short-term measures (such as temporary downgrading or closure) would be applied to affected areas (or zones where applicable), until sampling results show levels of *E. coli* contamination are compliant with the legal limits for the underlying classification of the area in question.

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5 BASIS FOR LTC PROPOSALS

- 5.1 None of the A class areas in England and Wales currently has data over a five year period showing compliance with the legal requirements for sample results (i.e all results for the period below 230 *E. coli* per 100g of flesh). To qualify for B class status, EU legislation requires results of samples to meet 90% compliance with the limit of 4600 *E. coli* per 100g of flesh. B class beds currently account for over 80% of all designated shellfish harvesting areas in England and Wales. Of the current 295 B class areas, 237 have data for the last five years which meet the criteria laid down in the Directive. In view of this it is proposed that the LTC arrangements should, in the first instance, apply to B class areas in England and Wales.
- 5.2 Areas meeting the LTC criteria (237/295 shellfish areas in England and Wales) would be assigned a classification status, based on this data, for five years. The remaining 58 areas which currently do not meet the criteria, including new commercial shellfish harvesting areas, would be subject to temporary classifications, which would be reviewed annually.
- 5.3 Where known sewage discharge improvements have been made and data exists to demonstrate that the underlying quality of the water has significantly improved over a three year period, the Agency may consider, on advice from CEFAS, recommending these sites for inclusion in the LTC system.
- 5.4 The status of all areas included in the LTC system would continue to be monitored to ensure water quality standards are maintained and that there are no underlying long term changes. In the event of persisting deterioration in water quality, affected areas may lose their LTC status. All recommendations would be based on the statutory classification data and trend analysis.
- 5.5 Further details of the process are described in TREE 1 (Annex 3) and TREE 2 (Annex 4)
- 5.6 Areas with a mix of A and B classifications over the last five years may be eligible for inclusion in the LTC scheme, but harvesters, in agreement with the LA, may choose to remain in the temporary classification scheme until the LTC arrangements are reviewed (two years after implementation). Similarly it is proposed that B class areas that satisfy the LTC criteria, but which subsequently achieve two years' worth of class A results would be permitted to opt out of the LTC and revert to the temporary classification scheme. The approach to be taken in such situations would be decided on a case by case basis in consultation with the LAG and the FSA.
- 5.7 Once the effectiveness of the scheme has been reviewed, the Agency would consider whether the approach should be extended to include A and C class areas in the LTC system.

6 MONITORING THE CLASSIFICATION STATUS OF SHELLFISH AREAS

6.1 Currently, with the exception of A class areas, no action is taken in the event of a single high *E. coli* result until the annual classification review. In most cases investigations are only undertaken when the limit is exceeded for the second time, to determine if the result was due to an exceptional pollution event i.e. high rainfall and can therefore be waived. Depending on the outcome an interim change can be made to the Classification of the area, but no other action is taken in relation to results exceeding the criteria. To strengthen the arrangements, it is proposed that an action state should be introduced for A, B and C class areas when levels of contamination exceed defined trigger values, and this would last for a maximum period of three months. These arrangements are described in more detail in paragraphs 6.3 to 6.22.

6.2 In the case of B class areas, a graduated approach has been developed to facilitate prompt investigation of abnormal results and appropriate immediate action to protect public health. The extent of the measures would depend on the *E. coli* levels detected. As a minimum, every result from a B class area which exceeds the statutory levels would be investigated, and the findings acted upon. Control measures would be implemented as appropriate. These are described in more detail in paragraphs 6.5 to 6.12.

Action States

6.3 An 'action state' would involve:

- Prompt short term control measures by local authorities to ensure immediate public health protection when trigger values are exceeded
- Investigative measures to identify the cause (LAGs and CEFAS)
- Extra sampling to monitor the level of contamination, to assess whether the underlying long term quality of the water has changed and to aid decision making

These arrangements would not be expected to significantly add to the burden or cost to LAs, but are expected to increase the effectiveness and timeliness of control measures at the local level, and result in more active management.

Action State Trigger Values

6.4 The proposed action state triggers are:

- A class above 230 *E. coli*/100g of flesh;
- B class above 18000 *E. coli*/100g of flesh
- C class above 46000 *E. coli*/100g of flesh

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The A and C class action state trigger values have been set to co-incide with the upper *E. coli* limits allowed by EU legislation for these classifications. For practical reasons, a different approach is being proposed for B class areas.

6.5 Based on 2003 data for B class areas, which are shown in Annex 5, a trigger level at the upper *E. coli* limit allowed by EU legislation (4,600 *E. coli*/100g of flesh) would have led to 139 action states. Dealing with this number of action states in one year would have significant resource implications and could be expected to result in a greatly increased burden for LAs, CEFAS and the testing laboratories. In order to achieve improved consumer health protection in a way which is manageable given existing resources, it is proposed that action is graduated.

6.6 It is proposed that all B class areas giving a test result in excess of 4600 *E. coli*/100g of flesh would, as a minimum, be investigated. However, at levels above 18000 *E. coli*/100g of flesh, an action state would be initiated. It should be emphasised that, under current arrangements, no action is taken in response to a single high *E. coli* result, so the approach being suggested would represent an increased level of action. Based on data from 2003, such criteria would result in 14 action states during a year. This risk based, tiered approach is considered proportionate and has the advantage of directing action to where it is most needed. The tiered approach is described in more detail below.

First Tier - Initial Investigations

6.7 A sample from a B class area giving a result between 4600 and 10000 *E. coli* per 100g would trigger the first tier of investigation. This would involve verification of the result and a statistical assessment, to determine whether a significant change in the general level of contamination has occurred. The initial investigation would be carried out by the Environment Authority (EA) and the LA to identify the cause of the high result. CEFAS would carry out the statistical assessment to assess whether there had been any change in water quality.

6.8 If the investigation suggests a change in the underlying quality of the water then consideration would need to be given to further action to ensure that public health is protected. However, it is not expected to lead to temporary closure or down grading of the shellfish areas although the results would be taken into account when assessing the underlying long-term quality of the water.

Second Tier - Formal investigations

6.9 A sample from a B class area giving a result between 10000 and 18000 *E. coli* per 100g of flesh would trigger the second tier of investigation which would involve a “formal investigation” by a LAG to assist in identifying the cause. Data from the statistical assessment carried out by CEFAS to

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determine if there had been a change in water quality would feed into this process. The LA would be responsible for identifying any action which may be required and ensuring it is taken. The investigative process is set out in TREE 3 (Boxes 1-6 Annex 6).

6.10 It should be stressed that this is not an action state and would not generally involve temporary closures or down grades of an area, nor would it in itself lead to increased sampling of the water. The move to an action state may be considered if the cause of contamination could result in an increased risk to public health. Depending on the outcome of the investigation and statistical analysis, the result would be taken into account when assessing the underlying long-term quality of the water.

Third Tier – Action State

6.11 At levels above 18000 *E. coli*/100g of flesh, an action state would be initiated for B class areas. This would be activated by the Agency who would notify the LAG who in turn would be responsible for implementing the Local Action Plans (LAPs).

6.12 Once an action state has been activated, the LA would be responsible for putting in place appropriate short term measures to protect public health (i.e. Temporary Prohibition Order (TPO), temporary downgrade or closure). These would remain in place while investigations are carried out, and until the *E. coli* levels revert to within legal levels and the action state is lifted by the Agency. The action state would be in place for a maximum of three months. During this period the LA would also be required to collect extra samples for *E. coli* monitoring purposes.

Action State - Short Term Public Health Control Measures

6.13 Once an action state has been initiated, decisions on the most appropriate short term control measures to be applied will be decided by the LAs, after consultation with the FSA. Consideration would also be given to any action required in relation to the product already in distribution.

6.14 If a temporary downgrade were considered necessary, the FSA would notify the relevant LA who in turn would be expected to notify all other interested parties via the LAG. In the case of beds downgraded from A to B all shellfish from the affected area would be required to undergo depuration for the specified period and meet the end product standard of below 230 *E. coli*/100g of flesh before being placed on the market.

6.15 If a temporary closure is required then the LA with responsibility for the area would be advised by the FSA to issue a TPO.

6.16 Measures would be lifted once action state sampling had shown that the *E. coli* levels had returned to below the legal limits for the classification.

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Action State – Investigations

6.17 Once the short-term measures are in place an investigation into the cause of the abnormal result would be initiated. These investigations would be instigated by CEFAS and would be led by the LA but would involve the LAG. Further details are set out in TREE 3 (Annex 6) and the action state – guidance for local action (Annex 2).

Action State – Sampling Arrangements

6.18 The action state short term public health measures (described in paragraphs 6.13 to 6.16) would be implemented by the LA immediately after notification of a result exceeding the action state trigger value. With these measures in place, extra samples would then be taken at designated intervals by the LA to monitor the *E. coli* levels and provide data to help decide when to lift the action state control measures.

6.19 It is proposed that 2 clear samples (i.e. within the classification threshold for the bed concerned) taken 7 days apart, should be required before control measures are lifted. This interval has been set in recognition of the different clearance rates between *E. coli*, and viruses. CEFAS has advised that there is currently insufficient information available to recommend a shorter interval between sampling without potentially exposing the consumer to a significant risk. However, the proposed minimum closure period will be reviewed in the light of experience backed up by relevant research and development work.

6.20 The first test following a high result would be taken no later than seven days after the original high result sample. If this sample showed a result complying with the values set for the classification then a further sample would be taken seven days later. The temporary measures would be lifted if the results complied with the classification value provided there were no other implications for public health protection. If they were not satisfactory then the action state would continue to apply until data from subsequent monthly sampling, up to a maximum period of three months, demonstrated that *E. coli* levels met the criteria. If results do not show compliance with the classification values by the end of the three month period then an underlying trend may exist and a decision would need to be made on the status of the classification. In reaching this decision, historical data, local information and advice on sewage outflows would be taken into consideration.

6.21 Any extra samples taken as part of the action state investigations would not be included in future classification assessments (temporary or LTC) because they would skew the results and would not give a true reflection of the water quality over the classification assessment period. However all of the results from the routine monthly samples would be taken into account when assessing the ongoing status of temporary or LTC areas (with the exception of those clearly associated with an exceptional event).

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7. TIMING

7.1 In accordance with Government procedures, the consultation on these proposals will run for a period of three months and will close on [] July 2004. All responses will be published together with the agreed LTC scheme.

8. NEXT STEPS

8.1 Review responses to consultation exercise on the proposals to improve the classification arrangements for designated harvesting areas in England and Wales. If appropriate, modify LTC scheme in the light of responses.

8.2 Review the classification arrangements after two years to evaluate their effectiveness, and consider if any further improvements could be made. At that stage the FSA would also consider whether the LTC scheme should be modified in any way, such as extending it to Class A waters.

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ANNEX 1: CLASSIFICATION ARRANGEMENTS

1. Directive 91/492/EEC requires member states to establish a sampling and testing programme to ensure that shellfish are harvested from areas with known microbiological status. Using the results of the sampling and testing programme, shellfish harvesting areas must then be 'classified' according to criteria outlined in the Directive. The classification assigned to a harvesting area determines the level of treatment, if any, that shellfish from that area must undergo before being placed on the market. The Directive also provides for the production and harvesting of bivalve molluscs to be prohibited on public health grounds in areas that have excessive levels of indicator organisms.
2. Shellfish harvesting areas are classified as A, B, or C, or harvesting may be prohibited in any area considered unsuitable for these activities for health reasons. To be classified as:
 - A class shellfish from that area must have less than 230 *E. coli* per 100g of mollusc flesh and intravalvular liquid;
 - B class shellfish from that area must have less than 4,600 *E. coli* per 100g of mollusc flesh and intravalvular liquid over 90% of samples;
 - C class shellfish from that area must have less than 46,000 *E. coli* per 100g of mollusc flesh and intravalvular liquid.
3. In England and Wales, food authorities collect shellfish samples from designated monitoring points in harvesting areas every month, which are then tested for levels of *E. coli* by accredited laboratories.
4. Monitoring points are agreed between CEFAS and the relevant local authority. Monitoring points take account of the nature and location of the shellfishery, position of sewage discharges, tidal flows, and local topographic details and are selected to reflect the likely variation in contamination across the shellfish harvesting bed. From a scientific viewpoint, the number of points necessary depends upon the complexity of the catchment, particularly the number of significant contaminating inputs (points that reflect the worst case scenario from a public health perspective). The results are reviewed and analysed by CEFAS every year to determine which class the harvesting area fits within. The FSA makes the final classification decisions, which are then issued to harvesting areas. Where an area fluctuates between two classes, historical data and results from neighbouring sites are considered before a decision is made.
5. It is recognised that the monthly sampling programme does not detect short-term variations in microbiological concentration, however it does allow seasonal and tidal variations to be taken into account and to be incorporated into the long-term data set. To take account of variations due to the spring/neap cycle, for example, samples are taken on as random a basis as possible across the tidal cycle.

ANNEX 2

LOCAL ACTION GROUPS (LAGS) AND LOCAL ACTION PLANS (LAPS)

1. A LAG will be set up to assist LAs in investigating abnormally high results. Its primary function is to act as a conduit for effective and timely information exchange, contributing data which will be used to help inform decisions on appropriate health protection measures.
2. A LAG would be made up of representatives of the Local Authority, the Environment Agency, Sea Fisheries Inspectorate and members of the local industry. In certain areas the LAG function could be undertaken by Local Shellfish Liaison Committees. The Local Authority representative would lead the LAG and be responsible for taking decisions on the information obtained.
3. A LAG would be responsible for developing a Local Action Plans (LAP), which will formalise the procedures to be followed when:
 - *E. coli* levels exceed 10,000 for B class areas
 - An action state has been activated.
4. A LAP would be expected to account of and provide a means of gathering data relating to local factors or conditions which may affect test results and to identify a checklist of parameters which should be applied when investigating abnormal readings. It would also be expected to include a contact list to ensure speedy exchange of information and resolution of investigation. Guidance on these arrangements is attached.

ACTION STATE – GUIDANCE FOR LOCAL ACTION

INTRODUCTION

1. An action state is being introduced into the shellfish classification arrangements in England and Wales to deliver a more responsive public health control system. It will consist primarily of 2 phases: the first will involve the implementation of prompt and appropriate short-term health control measures. The second is an investigation into the cause(s) of high results to determine their relevance to the classification of the area and also to allow identification of remedial measures in order that such events can be avoided (or more effectively dealt with) in the future. It is intended that the action state system should be applied to all areas regardless of whether they are under LT or temporary classifications. An action state will last for a maximum period of three months.
2. The statutory organisations primarily involved under an action state would include FSA, Local Authorities, the Centre for Environment, Fisheries & Aquaculture Science (CEFAS) and the Environment Agency. Other interested parties that may be able to feed into the investigative process of

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an action state would include shellfish liaison groups, local industry bodies and Sea Fisheries Committees.

ACTION STATE PROCEDURES

3. Initial notification will come from **CEFAS** who will be advised by the local classification testing laboratory of the results of the classification sample. Known pollution events (without monitoring) may also cause an action state to be activated. If the *E. coli* result exceeds trigger values (**A class above 230; B class above 18000; C class above 46000**), **CEFAS** will notify the FSA (Fish and Shellfish Branch H) and the relevant Local Food Authority of the result. In accordance with the requirements of LTC, the **FSA** will then advise the Local Authority of the action state short term measures to be put in place for the relevant area, for the period of the action state investigation (maximum of 3 months). The **Local Authority** will then notify the local industry of the status of the harvesting area. Industry members with interests in the affected area(s) should be contacted as soon as possible so that short-term actions may be implemented without delay. Local Action Plans (LAPs) will be drawn up to help facilitate effective communications and overcome any problems with contacting industry members in non-regulated fisheries, particularly those where non-local harvesters are often active.

ACTION STATE - SHORT-TERM CONTROL MEASURES

4. High levels of *E.coli* in water represent a public health risk and so a Temporary Prohibition Order or temporary downgrade may be necessary. Possible options will be as follows: -
 - Class A.** One result above 230 but below 18,000: temporary downgrade to B; If above 18,000 temporary downgrade to C or closure;
 - Class B.** One result above 18,000: temporary downgrade to C or closure; and
 - Class C.** One result above 46,000: temporary closure
5. Under certain circumstances e.g. where sites are formally closed by SFC by-law or other formal means no short-term action may be needed. Up-to-date details of such closures should **therefore be kept by Local Authorities** to aid the decision making process. Written voluntary agreements may be appropriate for farmed fisheries, however, more formal procedures (e.g. TPOs) may be necessary for public fisheries. Short-term control measures should also be considered following identified pollution events or outbreaks related to particular harvesting areas even where monitoring data is not available.

On notification of an action state Local Authorities will:

- verify result triggering action state with local HPA laboratory (trigger criteria as above)

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- on receipt of advice from FSA apply short-term control measures for relevant area
- implement the Local Action Plan (LAP) advising local industry of short term measures and seeking the cause of the high reading(s)
- liaise with CEFAS on sampling programme
- liaise with the local EA contact where appropriate
- consider whether any action is required in relation to product already in distribution

CEFAS will:

- review existing data for the monitoring point and neighbouring points.
 - apply statistical analysis to the data to assess underlying trend
 - contact relevant EA personnel to inform them and seek information re cause(s)
 - following completion of investigations prepare, in liaison with LA, a summary for FSA including recommendations.
 - Agree sampling regime with LA and inform FSA.
6. The legal basis for short term closures comes from Part II section 7 of the Food Safety (Fishery Products and Live Shellfish) (Hygiene) Regulations 1998: '...a food authority may, if it is satisfied that the consumption of live shellfish taken from a production area is likely to cause a risk to public health, make a temporary prohibition order prohibiting the collecting of any live shellfish from that area. Results higher than the defined trigger values in this case should be deemed to be sufficient indication of a 'likely risk to public health'
7. No distinction is currently made between animal and human faecal contamination. Animal sources, according to current knowledge at least, may not pose a problem from the viral point of view but may contain bacteria and protozoa capable of causing human disease and consequently should be considered as a hazard.

Action State - Sampling and closure/downgrade periods

8. Following high readings, *E. coli* levels in shellfish often rapidly reduce to background levels. Viral and other pathogens may, however, persist for a considerable length of time. In recognition of this, and to allow time for some natural clearance to take place, **Local Authorities should carry out the first sample no later than 7 days after a trigger result (or the end of a spillage) with a second sample being taken seven days after the first additional sample . Both of these results need to be below the normal classification value (i.e. <230, <4600 or <46000 for A, B and C respectively) before the control measures are lifted.** The minimum closure/downgrade period may therefore be 10/14 days. If the results of these investigative samples are unsatisfactory, then the closure/downgrade would continue to apply but sampling would revert to

CLASSIFICATION OF SHELLFISH HARVESTING AREAS

the monthly classification samples for that area (e. weekly sampling will only apply to the first two weeks of an action state). The maximum period of an action state would be three months (including the initial period).

9. If these samples still do not comply with the relevant classification thresholds then an underlying trend may exist and consideration would need to be given as to whether the bed should be downgraded on a longer-term basis. **Extra 'investigative' samples will not be included in the classification assessment (unless they happen to fall at a time when a routine monthly sample is to be taken).** All routine monthly monitoring results will be included (including those triggering an action state) unless they meet the exceptional event criteria below. **It should be noted that identification of a cause (even with short-term action) is not grounds for waiving a result in itself and only if the exceptional criteria are met will a waiver be considered. Identification of cause wherever possible is vital in ensuring appropriate and effective remedial action is taken both in the short and longer term.**
10. It should be noted that 10/14 days might be insufficient time to allow clearance of all contamination (viruses) when water temperatures are low in the winter months. **Local Authorities and the FSA** may, therefore, wish to consider the position where known and particularly large pollution incidents have occurred.

Exceptional event criteria

- ◆ 1 in 5 year major storm event
- ◆ major sewage treatment works failure (since rectified)
- ◆ other exceptional pollution event (e.g. slurry spill)
- ◆ failure to comply with the sampling protocol (e.g. failure to test sample within 24 hrs of collection)

CEFAS to assess significance of event in terms of impact at monitoring point and thus whether they would recommend to the FSA that the result should be waived.
Long Term Classification of an area

Investigations - Local Action Plans

11. **It is proposed that a draft template for local action plans will be drawn up and circulated for comment if the proposals are agreed.** These plans would identify local factors to help with speedy investigations and outline possible control measures to be implemented during an action state. They would also include a list of industry contacts for notification purposes. Where appropriate it is envisaged that all groups should play a key role in the development of local action plans, Site specific action plans should be agreed locally in advance with all interested parties, including the industry, (using the short-term control measure items below as a guide) for those scenarios that are considered likely to occur. As a minimum this should include:

CLASSIFICATION OF SHELLFISH HARVESTING AREAS

- breach of the relevant classification trigger for that site
- a known gross pollution event (with or without monitoring data).

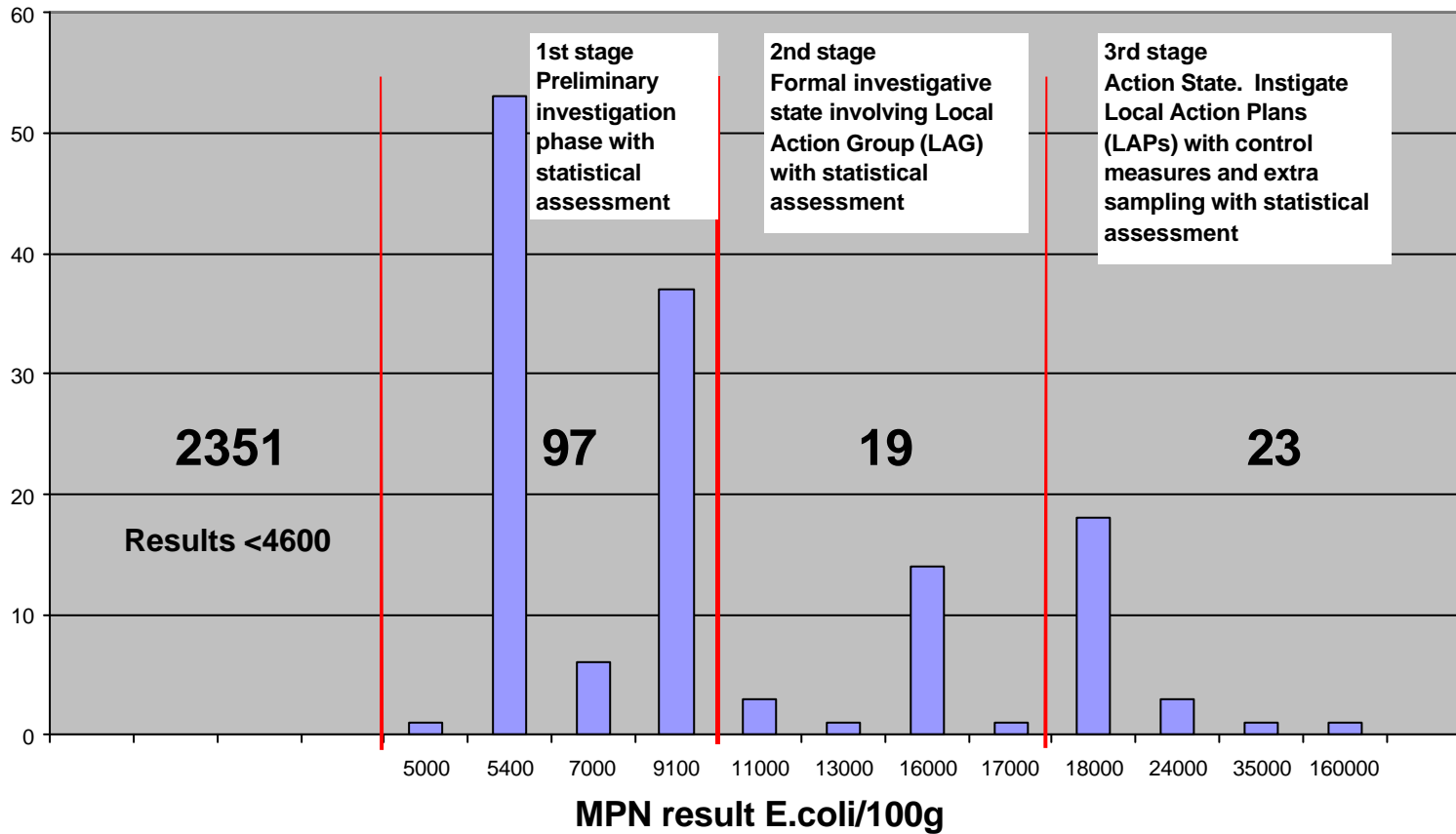
Examples of other occurrences for which plans may also need to be considered are:

- exceptional rainfall or other climatic event
- unusual dredging activity
- unusually high level of recreational or other boating activity

Ending the Action State

12. The **FSA** will advise Local Authorities and CEFAS when an action state has ended and the short-term measures may be lifted. **Local Authorities** will advise the local industry of the ending of an action state. It may be necessary to review the Local Action Plans in the light of events that gave rise to the action state. The FSA will advise on this.

Spread of E.coli results exceeding 4600 in class B areas - 2002/3



CLASSIFICATION OF SHELLFISH HARVESTING AREAS

TREE 1

Temporary classifications

Table 1
Requirements for new areas -minimum 3 month period covered – 10 results per point (Temporary classification) (*E.coli/100g*)

Class A 100% compliance with <230
Class B 90% compliance with <4600
Class C 100% compliance with <46000

Table 2 Trigger values (*E.coli/100g*)

Investigative State
Class B >10,000
Action State
Class A >230
Class B >18000
Class C >46000

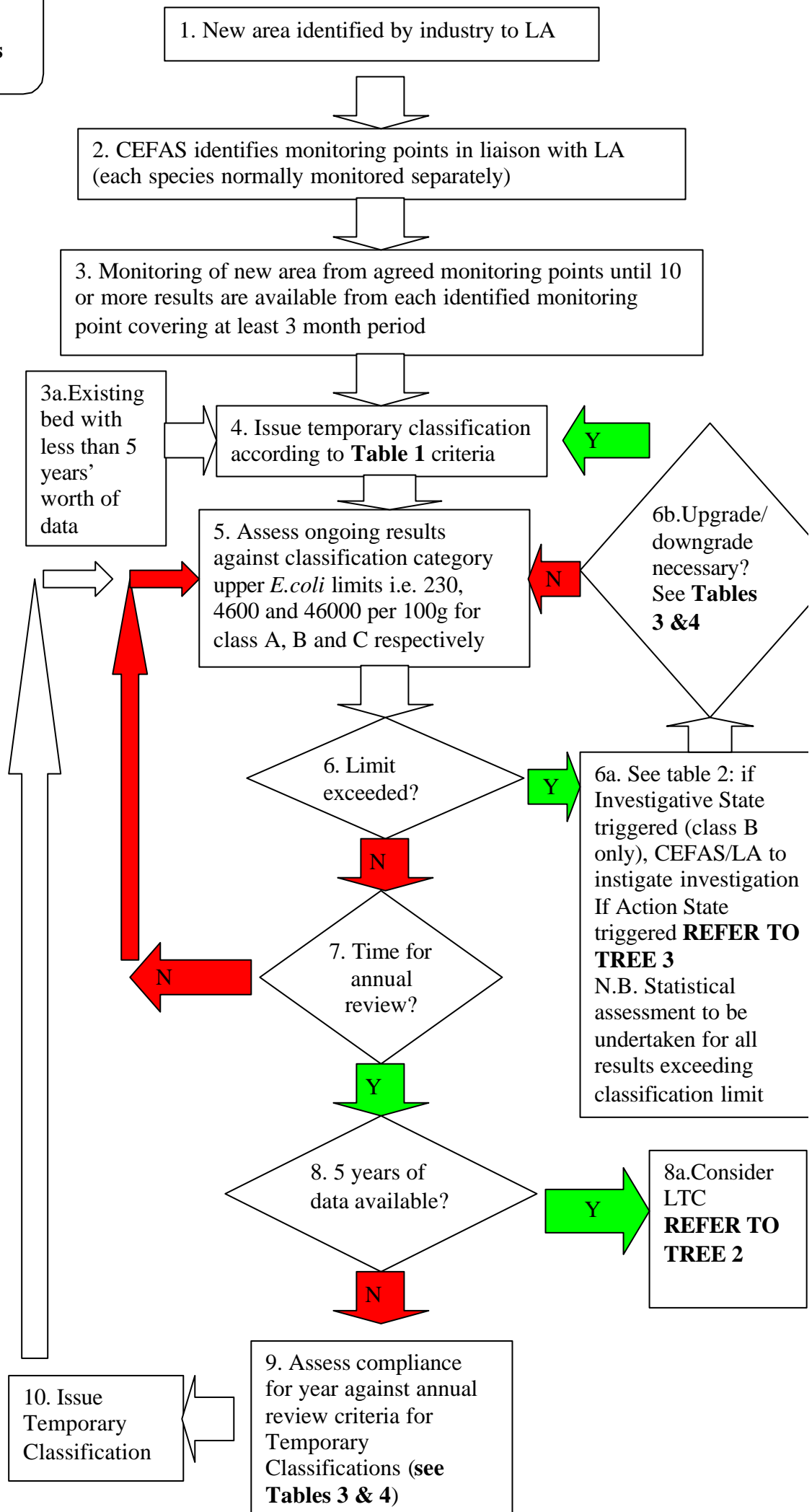
Table 3 Criteria for upgrades – assessment applied over 1 year's data (Temporary classification): (*E.coli/100g*)

At least 10 results over 1 year complying with the criteria in table 1 are needed for upgrades to class A and B and 20 results over 2 years to rescind prohibition to class C.

Table 4 Criteria for downgrades - assessment applied over 1 year's data (Temporary classification): (*E. coli/100g*)

Class A: 2 results >230 but <1000 or 1 result >1000
Class B: 3 results >4600 or 2 results >18000
Class C: 2 results >46000

Information on changes in polluting inputs and statistical analysis may be used as supporting evidence for upgrades and downgrades



1. Area with 5 years' data and no known polluting input changes in that time

1a. Area with 5 years' data and known polluting input changes in that time. Post change dataset shows statistically significant improvement in quality of results

TREE 2

Long term classifications (LTC)
Applies to class B only

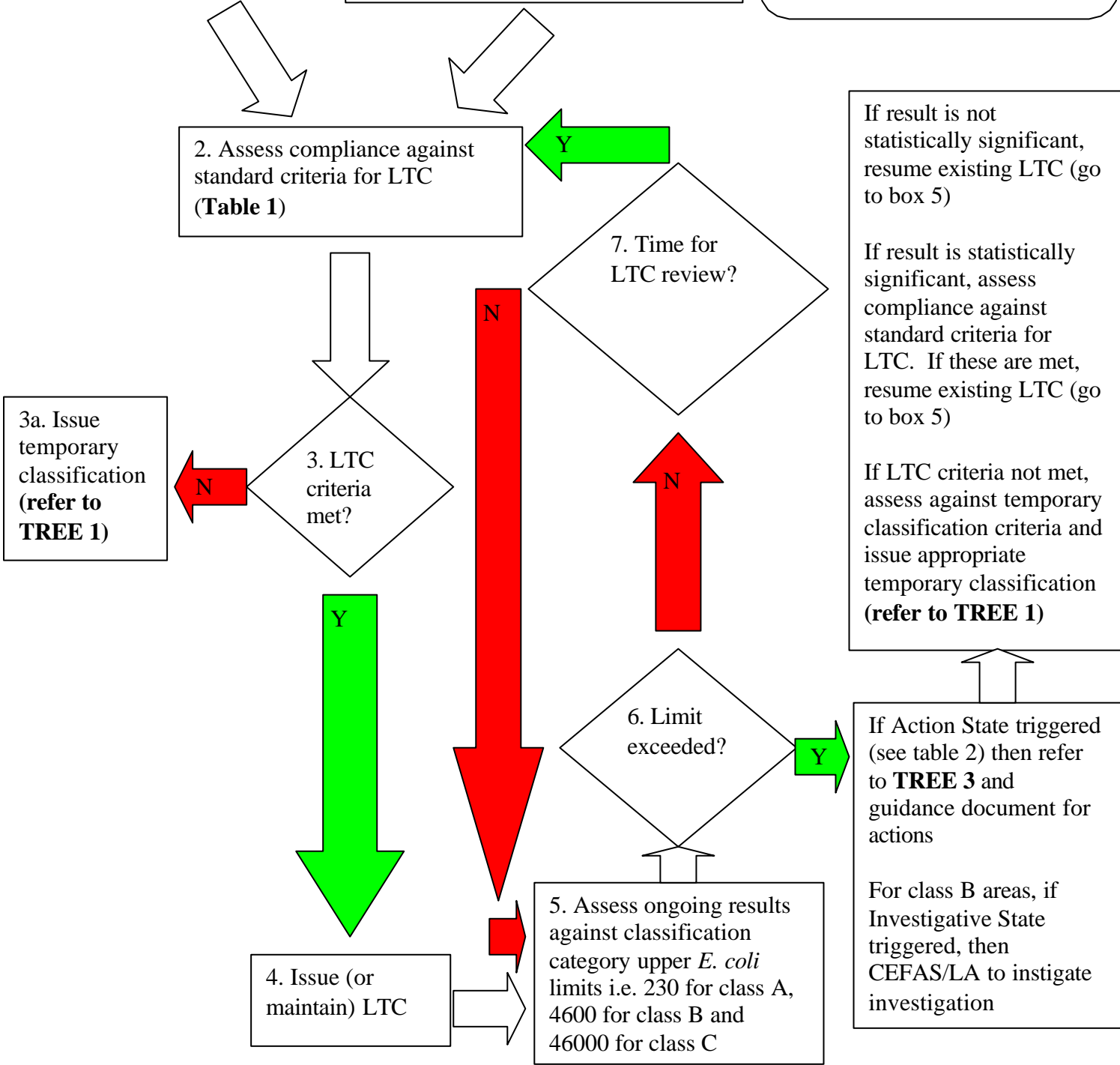


Table 1
LTC criteria (class B only):
90% compliance with 4600 *E.coli*/100g over 5 years

Areas with changes in polluting input within the last 5 years may require fewer data post-changes if dataset indicates a statistically significant improvement.

Table 2
Trigger values (*E.coli*/100g)
Investigative state
Class B >10000
Action State
Class A >230
Class B >18000
Class C >46000

Information on changes in polluting inputs and statistical analysis may be used as supporting evidence for upgrades and downgrades

1. Receipt of result above trigger value (see Table 2)

2. FA to verify that result is valid

3. Result valid?

N

3a. Resume normal operation
Refer to Tree 1 or 2 depending on classification type

Y

TREE 3
Action state
Applies to all classifications

Table 1 Exceptional events

- ◆ 1 in 5 year storm event
- ◆ major sewage treatment works failure (since rectified)
- ◆ other exceptional pollution event (e.g. slurry spill)
- ◆ failure to comply with sampling protocol

Table 2 Action State trigger values and actions

Short-term control measures:

voluntary closure agreement, TPO or temporary downgrade may be necessary. As a guide:

Class A. If result >230 but <18000: temporary downgrade to B. If >18000 temporary downgrade to C or closure.

Class B. If result >18000: temporary downgrade to C or closure.

Class C. If 1 result >46000: closure

Short-term control measures should also be considered for known pollution events (without monitoring) or for outbreaks

4. Action State activated (follow Action State Guidance document)

Organisations primarily involved: **LAs, CEFAS, FSA, local industry, and EA.**

- **Other interested parties:** shellfish liaison groups, Sea Fisheries Committees.

On receipt of information from CEFAS, LAs should:

- consider short-term control measures in liaison with CEFAS/FSA and local action plan (see Table 2)

Whilst investigations are taking place locally with EA and local action group etc, CEFAS should:

- review existing data for the monitoring point and neighbouring points.
- apply statistical analysis to the data to assess underlying trend (statistics only to be used to assist in the decision making process)

Temporary closure/downgrade period: No testing until 7 days after a trigger result/spillage. Two consecutive clear samples (i.e. <230, 4600 or 46000 for A, B and C respectively) taken 7 days apart needed before normal operation resumed. If results and investigations are unsatisfactory then area moves to temporary downgrade for 3 month period (monthly monitoring).

5. Results of testing and other data

6. If pollution event known to be over and 2 clear samples have been returned, FA/CEFAS/FSA to consider lifting short term closure/downgrade

7. If result due to exceptional event (see table 1) then waive, otherwise add to database

8. If result is not statistically significant, resume existing classification. If result is statistically significant, assess compliance against criteria for relevant classification type and existing category (see **Trees 1 or 2 as appropriate**). If these are met, resume existing classification.

For both classification types, if criteria are not met, assess/reassess against Temporary Classification criteria and issue appropriate Temporary Classification (see **Tree 1**)